

Appl. No. 10/727,100
Amdt. dated August 16, 2007
Reply to Office Action of February 16, 2007

PATENT

Amendments to the Drawings:

Please replace sheets 1, 2, 5, and 8 with the attached replacement sheets.

REMARKS/ARGUMENTS

The specification has been revised to address various minor informalities, and to delete redundant information from the specification as explained below.

Claims 14, 22, 23, 31, and 39 have been revised to address minor informalities in language without altering the scope of the claims.

Claims 10, 11, 17, 18, 26, and 27 have been revised to remove the term "derived". No narrowing of claim scope is intended or believed to have occurred.

Claim 23 has also been revised to be better tailored to currently contemplated commercial embodiments of the invention without acquiescence to any alleged rejection.

Claims 32 and 39 have been revised as supported in paragraph [0036] in the instant application (see US 2005/0239079).

Claims 54, 55, 58-62, and 65-67 have been revised to use alternative language to encompass the same intended subject matter.

No new matter has been introduced, and entry of the above amendments is respectfully requested.

Initial matter

Applicants point out an error on form PTOL-326 and its continuation sheet in the identification of the pending claims. Specifically, Applicants believe that the pending claims are 7-23, 25-33, 35-40, 42-44, 46, 47, 54-56, 58-63, and 65-73. Clarification in the next Office Communication is respectfully requested.

Restriction Requirement

Applicants acknowledge the recombination of claims as set forth on pages 2-6 of the Office Action. This includes the indication that Group II would be rejoined with Group I. This is confirmed by the indication of (previously Group II) claims 8-9, 15-17, 20-22, 25-26, 29-31, 56, 68, and 69 as having been searched and examined.

And while Applicants also acknowledge the recognition of genus claims, Applicants are confused as to the withdrawal of certain claims from consideration. These claims appear to have in the common the feature of detection by either polypeptide or methylation status. Withdrawal of these claims from consideration again reflects an improper "restriction within a genus claim" which is barred for the reasons provided in Applicants previous response to Restriction. Therefore, Applicants respectfully submit that the withdrawn claims should be searched and examined unless there was an unexplained requirement for election of species election (among detection by nucleic acids, polypeptides, and methylation status) and an election of nucleic acids without Applicants approval. Clarification in the next Office Communication is respectfully requested.

Priority

Applicants acknowledge, but disagree with, the statements on pages 7-8 of the Office Action. Applicants respectfully submit that there has not been sufficient consideration provided to the descriptive support present in the priority document. But given the absence of any rejections based upon cited documents with a disclosure date, Applicants believe that no further discussion of this issue is necessary.

Drawings

The drawings were objected to due to various informalities. With respect to Figures 1, 2, 5, and the second sheet containing Figure 7, replacement sheets are submitted herewith. With respect to Figures 3, 6 and the first sheet containing Figure 7, Applicants respectfully submit that no label on the vertical axes is needed in light of the content in the instant specification.

Sequence Compliance

Page 10 of the Office Action presents a requirement for the Appendix in the instant application (on pages 75-188) to comply with the Sequence Rules. Applicants respectfully submit that the Appendix was presented in the application on filing to stand in place

of a Sequence Listing. Now that a Sequence Listing is present in the application, the presence of the Appendix constitutes an unnecessary duplication of information found in the Sequence Listing. Therefore, Applicants have deleted the content from pages 75-188 as presented above, and revised the remainder of the application accordingly.

The requirement for sequence compliance is thus believed to be obviated, and so it may be withdrawn.

Specification

The specification was objected to based on informalities in three tables as presented. The specification has been revised on pages 25, 32, and 36 to address this issue. This objection is thus believed to be obviated, and so it may be withdrawn.

Claim objections

Claim 14 was objected to based on a requirement to “spell out” an abbreviation. As presented above, claim 14 has been revised as presented above, and this rejection may be properly withdrawn.

Claims 22 and 31 were objected to as lacking “proper subject/verb agreement.” These claims have been revised as presented above, and this rejection may be properly withdrawn.

Claim 26 was objected to as comprising “non-elected subject matter.” Applicants respectfully traverse for the reasons presented above in connection with the Restriction Requirement. Reconsideration and withdrawal of this objection is respectfully requested.

Alleged claim rejections under 35 U.S.C. § 112, second paragraph

Claims 10, 11, 17, 18, 23, 26, 27, 32, 33, 39, 40, 43, 54, 55, 58-62, and 65-67, along with dependent claims 25, 29-31, 35, 42, and 63, were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Claims 10, 11, 17, 18, 26, and 27 were rejected based on the alleged indefiniteness of the phrase “derived from”. Applicants have carefully reviewed the statement of

the rejection and respectfully traverse because no *prima facie* case of indefiniteness is present. Simply put, the term is broad, but breadth is not indefiniteness. But to advance prosecution without acquiescence to this rejection, the claims have been revised to remove the term “derived”. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Claim 23 was rejected based on the alleged indefiniteness of the term “appropriate treatment”. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of indefiniteness is present. Simply put, the term is broad, but breadth is not indefiniteness. But to advance prosecution without acquiescence to this rejection, the claim has been revised to remove the term in favor of alternative language. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Claims 32 and 39 were rejected based on the alleged indefiniteness of “increased or decreased expression”. To advance prosecution without acquiescence to this rejection, the claims have been revised to include a relationship to “normal expression levels”. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Claims 33, 36, 40, and 43 were rejected based on the alleged indefiniteness of the term “such as” and the MPEP at 2173.05(d). Applicants respectfully traverse because the term is believed permitted under the standard set forth at MPEP 2173.02. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 54, 55, 58-62, and 65-67 were rejected based on the alleged indefiniteness of the claim in relation to the claims from which they depend. The claims have been revised to use alternative language to encompass the intended scope. Therefore, reconsideration and withdrawal of the instant rejection is respectfully requested.

Alleged claim rejections under 35 U.S.C. § 112, second paragraph

Claims 7-11, 14-18, 20-23, 25-27, 29-33, 35-36, 39-40, 42-43, 54-56, 58-63, and 65-69 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an enabling disclosure. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of non-enablement is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

The rejection alleges that sequences “critical or essential to the practice of the invention are not enabled by the disclosure.” Applicants respectfully, but strongly, disagree because the instant application contains multiple representative species of HoxB13 and IL17BR gene sequences in the Appendix and Sequence Listing as filed. Additionally, the specification expressly describes the use of any HoxB13 or IL17BR sequences of the corresponding human HoxB13 and IL17BR gene clusters, respectively. Representative sequences from those clusters are presented in Table (i) for IL17BR and Table (iii) for HoxB13, while the specific sequences of these representatives were provided via the Appendix and the Sequence Listing.

Therefore, Applicants respectfully submit that contrary to the instant rejection, there is no improper incorporation by reference of sequence information.

Additionally, Applicants point out the recent Federal Circuit guidance in *Capon v. Eshhar* (76 USPQ2d 1078 (Fed Cir 2005)) which expressly held that there is no need to disclose sequence information that is known in the art. Applicants respectfully submit that the HoxB13 and IL17BR gene sequences are examples of such known sequences, as shown by the multiple sequences present in each cluster, and there has been no evidence provided to contradict this position. Therefore, no *prima facie* case is present, and this rejection may be properly withdrawn.

Claims 7-11, 14-18, 20-23, 25-27, 29-33, 35-36, 39-40, 42-43, 54-56, 58-63, and 65-69 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an enabling disclosure. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of non-enablement is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

As an initial consideration in traversing the instant rejection, Applicants point out the well established standard that an application must be taken as presumptively enabling unless there is objective reason to doubt the statements contained therein (see MPEP 2164.04 and the case decisions cited therein, such as *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). This presumption is present before any “determination of enablement” is to occur under the *In re Wands* factors as cited in the instant rejection. Applicants submit that no objective reason has been provided to doubt the presumption of enablement in the pending claims.

And while the instant rejection alleges that the claims are too broad, that there is inadequate guidance and working examples, unpredictability in the art, and a large amount of experimentation, Applicants point out that the ultimate determination is whether undue experimentation is needed to make and use the claimed invention. It is well settled that the presence of enablement does not mean the lack of experimentation. To the contrary, routine and/or repetitive experimentation is the opposite of undue experimentation and is clearly permitted as evident from the facts of *In re Wands*. Applicants respectfully submit that no more than routine and/or repetitive experimentation is needed to make and use the claimed invention.

Contrary to the instant rejection’s allegation regarding the nature of the invention, the claims do not require “knowledge of a correlation” between HoxB13 and/or IL17BR. Instead, the instant application provides this correlation as an inventive concept that allows the practice of the method based on this correlation.

The above reflects a fundamental misunderstanding of the claimed subject matter. Additionally, the references to van’t Veer et al., Wu, Lucentini, and Chen et al. are all non-dispositive because none of them relate to the particular HoxB13 and IL17BR sequences at issue. As for Ma et al., the comments in that document alone are insufficient to support an allegation of undue experimentation because only routine and repetitive experimentation are needed as follow-up to that document. This is demonstrated by multiple documents that recognize the contribution made by Ma et al., and so the instant application. These documents include

Jansen et al. (J. Clin. Oncol. 2007, 25(6):662-668); Jerevall et al. (Breast Cancer Res. Treat. 2007), and Goetz et al. (Clin Cancer Res. 2006, 12(7):2080-2087). Copies of which will be provided as soon as practicable.

In light of the foregoing, Applicants respectfully submit that no issue of non-enablement is present and this rejection may be properly withdrawn.

Claims 7-11, 14-18, 20-23, 25-27, 29-33, 35-36, 39-40, 42-43, 54-56, 58-63, and 65-69 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to be supported by an adequate written description. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because no *prima facie* case of an inadequate written description is present. Reconsideration and withdrawal of the instant rejection is respectfully requested.

The basis of this rejection appears to be that more representative species of HoxB13 and IL17BR sequences are needed. Applicants respectfully traverse because the skilled person is already apprised of what such sequences are based upon knowledge in the art, including sequence databases, and the ability to compare new sequences to known sequences in the art to identify unique characteristics. Additionally, and as explained above based on *Capon*, there is no need to disclose sequences that are already known in the art.

Therefore, Applicants respectfully submit that no issue of an inadequate written description is present and this rejection may be properly withdrawn.

Alleged provisional rejections based on nonstatutory obviousness-type double patenting

Applicants request that the requirement for a Terminal Disclaimer be held in abeyance until the claims are otherwise held allowable.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 425-681-1833.

Respectfully submitted,

Dated: August 16, 2007

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